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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,813	10/19/2004	Johannes Coy	4007.008	6538

30448 7590 06/23/2006

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EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/511,813	Applicant(s) COY, JOHANNES	
	Examiner Sean E. Aeder, Ph.D.	Art Unit 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 34-64 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

***Detailed Action***

***Election/Restriction***

**(Note: The Restriction Requirement of 12/8/05 did not take into consideration the Preliminary Amendment of 10/19/04. Therefore, the Restriction Requirement of 12/8/05 is hereby withdrawn. A new Restriction Requirement is set-forth below.)**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 34-38, 40, and 44-50, as specifically drawn to a method for detecting the presence or absence of human transketolase like-1 polynucleotide expression.

Group II, claim(s) 34-39, 41-43, and 50, as specifically drawn to a method for detecting the presence or absence of human transketolase like-1 polypeptide expression.

Group III, claim(s) 51-53 and 62, as specifically drawn to a human transketolase like-1 polynucleotide and a kit comprising a nucleic acid probe that specifically hybridizes to human transketolase like-1 polynucleotide.

Group IV, claim(s) 51-53, as specifically drawn to a kit comprising an antibody probe that specifically hybridizes to human transketolase like-1 polypeptide.

Group V, claim(s) 54-60, as specifically drawn to a method of treating disorders comprising administering a human transketolase like-1 polynucleotide.

Group VI, claim(s) 54-60, as specifically drawn to a method of treating disorders comprising administering a human transketolase like-1 polypeptide.

Group VII, claim(s) 61-62, as specifically drawn to a method for identifying and obtaining a drug candidate for therapy of tumors and compounds identified by said method.

Group VIII, claim(s) 62, as specifically drawn to an antithiamine compound.

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Group IX, claim(s) 62, as specifically drawn to an inhibitor of transketolase enzyme activity.

Group X, claim(s) 62, as specifically drawn to an inhibitor of transketolase like-1 activity.

Group XI, claim(s) 62, drawn to a human transketolase like-1 polypeptide.

Group XII, claim(s) 63-64, as specifically drawn to a method for rational tumor management comprising administering antithiamine compounds.

Group XIII, claim(s) 63-64, as specifically drawn to a method for rational tumor management comprising administering inhibitors of transketolase enzyme activity.

Group XIV, claim(s) 63-64, as specifically drawn to a method for rational tumor management comprising administering transketolase like-1 antisense constructs.

Group XV, claim(s) 63-64, as specifically drawn to a method for rational tumor management comprising administering ribozymes for transketolase like-1.

Group XVI, claim(s) 63-64, as specifically drawn to a method for rational tumor management comprising reduced administration of thiamine.

The inventions listed as groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XVI appears to be that they all relate to the special technical feature of the human transketolase like-1 gene. The instant specification discloses that the human transketolase like-1 gene corresponds to the GenBank Accession No X91817 (see page 3, in particular).

However, Coy et al (Genomics, 1996, 32:309-316) teaches the human transketolase like-1 gene corresponding to the GenBank Accession No X91817 (page 309 left column, in particular).

Therefore, the technical feature linking the inventions of groups I-XVI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XVI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 34-36, 54, 57, 58, and 61-63 are generic to a plurality of disclosed patentably distinct species of disorders and corresponding tumors comprising the following: colon cancer and colon cancer tumor, lung cancer and lung cancer tumor, gastric cancer and gastric cancer tumor (see claims 36 and 61, in particular). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. Further, the above species are distinct diseases which differ at least in etiology, pathology, and mechanisms. As such, each species requires different searches and the consideration of different patentability issues. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 34, 37, 38, 52, and 63 are generic to a plurality of disclosed patentably distinct species of samples comprising the following: serum, urine, semen, stool, bile, or a specific cell or specific tissue sample (see claim 38, in particular). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**